HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Refer to: CFN 1125547

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Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

March 19, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Stephen Ackerman, President
Spectrum Medical, Incorporated
8820 Brookville Road
Silver Spring, Maryland 20910

Dear Mr. Ackerman:

A Food and Drug Administration (FDA) inspection was conducted on March 2 and 3, 1999 at your medical gas manufacturing facility located in Silver Spring, Maryland. Medical gases are drug products as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Current Good Manufacturing Practice (GMP) requirements (Title 21, Code of Federal Regulations (CFR), Part 211) were observed. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, processing, packing, storage, or holding, are not in conformance with GMP regulations.

The deviations included the following:

- Failure to test and to document the testing of finished Oxygen, U.S.P. for identity and purity.
- Failure to document calibration of measurement equipment and that such equipment was calibrated against a known standard.
- Failure to quarantine untested containers.
- Failure to conduct hydrostatic retest within the scheduled period prior to release for use in manufacturing.
- Failure to establish and maintain complete production and process control procedures. For example, procedures do not address testing the purity and identity of finished products, acceptance or rejection of cylinders to be filled, hammer tests on steel cylinders only, fill and post-fill leak tests, documenting the serial numbers of tested cylinders, or the removal of old lot numbers prior to filling. Additionally, there was no documentation to show that all procedures had been dated, reviewed, and approved by appropriate individuals, including the quality control unit.

- Failure to maintain adequate batch production and control records, as batch records were either incomplete or documented inappropriate testing. On at least two occasions, your firm failed to document various fill and post-fill inspections conducted on each high-pressure cylinder used to manufacture Oxygen, U.S.P. Additionally, inappropriate hammer tests on aluminum cylinders were documented as having been performed.

- Failure to assign a unique lot number for each uninterrupted filling sequence of transfilled Oxygen, U.S.P.

At the conclusion of the inspection, Mr. Gary Gray, Service Manager, was presented with a written list of inspectional observations (FDA-483) which was discussed with him. A copy of the FDA-483 is enclosed for your reference.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facility. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when considering the award of contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,

Elaine Knowles Cole
Director, Baltimore District

Enclosure